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Playing God in the 21st Century: How the Push for Human Embryonic Germline Gene Editing Sidelines Individual and Generational Autonomy

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PLAYING GOD IN THE 21ST CENTURY: HOW THE PUSH FOR HUMAN EMBRYONIC GERMLINE GENE EDITING SIDELINES INDIVIDUAL AND GENERATIONAL AUTONOMY

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Every four and a half minutes a child with a genetic birth defect is born in the United States. For some, these conditions are treatable and manageable, but sadly for others, they are a death sentence. Congenital malformations and chromosomal abnormalities are the leading cause of infant mortality. CRISPR-Cas9 presents hope for the future, a liberation from the heritable genetic shackles that a child would otherwise be trapped in. With such optimism for future applications of germline gene editing, there are also great concerns with what national and global limitations and auditing must be in place to permit "genetic hedging."

Policy makers and the public must consider the fact that human germline gene editing does not just apply to family lines of those that consciously engage in genomic modification. It would eventually change the heterogeneity of humankind in the next stage of factitious evolution. Whose choice is it really to adopt this technology, and in what circumstances should the use of "genetic scissors" be morally, ethically, and legally permitted? May a parent consent on behalf of their unborn child? Will fetal interests supersede those of their parents? Or will government set aside individual, generational, and parental autonomy by mandating medical intervention in certain genetic circumstances?

This note debates current and potential American regulations on embryonic germline gene editing in the near future, and discusses the constitutional and ethical concerns that policymakers (and CRISPR-Cas9 critics) will appraise (and promulgate rules to safeguard against). For American regulation on germline gene editing, three events must occur: 1) The Federal Drug Administration ("FDA") rider must be repealed in future congressional appropriations bills, allowing for the FDA to consider clinical trials of embryonic research; 2) The FDA must adopt strict, narrow regulations allowing application of CRISPR in only a finite number of instances; and 3) the nature of an embryo must be firmly classified as quasi-property, therefore lacking constitutional standing as a legal "person."

There remains an issue: as fetal personhood legislation strengthens and becomes far more pronounced throughout the country, simultaneously, and more inconspicuously, so does embryonic personhood. Agency rights and constitutional protections attach upon the categorization as a "person," no matter how nascent life may be. If CRISPR were to be implemented in the wake of embryonic categorization as a recognized individual, the Due Process Clause and the Equal Protection Clause of the Fourteenth Amendment would be directly implicated.

The brilliance of CRISPR-Cas9 in human embryonic germlines makes a staggering promise: our next generation, and the generations thereafter, could be born into a world without susceptibility to HIV, cancers or various other genetic diseases. Like receiving prenatal genetic testing, in vitro fertilization, early intervention treatments, or even termination of a pregnancy, parents have a right to make decisions regarding the future of their pregnancy. These personal resolutions appear so intimate, yet they ultimately shape the composition of society. The fundamental rights to parenting and to privacy are certainly not plenary under current constitutional jurisprudence and modern interpretation of the Fourteenth Amendment. In balancing maternal and prenatal interests, there are instances where fetal health and viability are weighed against and supersede some of the decisions of the parents. This is particularly true with novel genetic intervention methods that have unforeseeable longitudinal effects.

Due to some of these conflicting rights implicating maternal and fetal autonomy, there are inevitable ethical, legal, and moral dissensions surrounding this technology. The current American conservative view on fetal personhood, as seen across various state legislatures and among the sitting United States Supreme Court justices, seemingly forecloses invasive genomic therapy at this time. However, this does not stop the global intrigue with germline gene editing, particularly as other nations have started to relax regulations that have previously prevented human trials for experimentation.

Here in the United States, should we blindly embrace the uncertainty that stems from "perfecting" the human genome? Or is a chase for mortal perfection a Pandora's Box that will further polarize our nation, and our world, on racial, socioeconomic, and medical access grounds, among others? It begs the question: should humanity be catalyzed to play God?

I. THE BEGINNINGS OF CRISPR

The human genome contains approximately 20,000 to 25,000 genes.[1] These genes assign themselves to coordinating base pairs that formulate the hereditary basis of that individual, as well as determining what proteins are necessary for the organism's function.[2] While 99.9 percent of the genome is identical across humans, the remaining 0.1 percent makes you unique.[3] Mutations may occur along transcribed DNA sequences as a result of viral infection, mutagen exposure (such as radiation), or erroneous DNA replication during cell division.[4]

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1 *What Is a Gene?*, MEDLINEPLUS,https://medlineplus.gov/genetics/understanding/basics/gene/ (Mar. 22, 2021).

2 *Id.*

3 *Id.*

4 *Id.*

In discussing gene therapy, there is an essential difference between somatic cells and germline cells. Somatic cell therapy seeks to cure a disease in the non-hereditary DNA of a living person.[5] In contrast to germline mutations, these DNA variations arise in the egg or sperm of the zygote's parent.[6] As such, they are heritable and can be passed on to offspring.[7]

A. CRISPR capabilities and the Promise of Radical Medical Intervention

Germline gene editing seeks to intervene prior to the implantation of a fertilized egg into a uterus by assessing and modifying antecedent eggs, sperm, cells, or early embryos in a laboratory.[8] A child would then be born with the guarantee that they would not suffer from the disorders or diseases that their parents had or carried, nor would they pass them on to their own future children.[9]

This is precisely what CRISPR does. This group of technologies allows for an existing DNA sequence to be located within the genome and manipulated.[10] Natural DNA repair mechanisms remedy the sequence post-therapy with deletions, insertions, or alterations of base pairs to create a desired result.[11] DNA is edited by mirroring the natural response that results when a virus is introduced into the body.[12]

The body attacks a virus by producing RNA to act as a messenger of the DNA's command.[13] This allows the virus to be targeted, and then enzymes are used to break the virus down.[14] In this technology, RNA is also used as a guide to identify the precise location of the mutated gene (similar to the identification of the virulent) and then interpolates the Cas-9 enzyme to cleave the DNA.[15] The concatenate double helix breaks with the enzyme, and then DNA naturally repairs that breakage with a re-directed "good" sequence instead of the sequence

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5 *Somatic Cells*, NAT'L HUMAN GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/Somatic-Cells (last visited Dec 15, 2023).

6 *Mutation*, NAT'L HUMAN GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/Mutation (Sept. 17, 2023).

7 *Somatic Cells*, *supra* note 6.

8 *Mutation*, *supra* note 7.

9 *See id.*

10 *CRISPR*, NAT'L HUMAN GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/CRISPR (Nov. 22, 2023).

11 Françoise Baylis et al., *Human Germline and Heritable Genome Editing: The Global Policy Landscape*, CRISPR J. 365, 365 (2020), https://www.liebertpub.com/doi/10.1089/crispr.2020.0082.

12 *What Are Genome Editing and CRISPR – Cas9?*, MEDLINEPLUS, https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/ (Mar. 22, 2022).

13 *Id.*

14 *Id.*

15 *Id.*

that coded for a mutation.[16] Through this germline gene editing process, the gene coding for an undesired expression is not only removed from the individual's genome, it is also extracted from the family's hereditary lineage as well.[17]

CRISPR was co-invented by Dr. Jennifer Doudna and Dr. Emmanuelle Charpentier, and their research was published in 2012.[18] They displayed how a natural human bacterial immune response to foreign nucleic acids may be mimicked and adapted with RNA and Cas-9 enzymes for gene therapeutic purposes.[19] This achievement was lauded throughout the scientific community, and both co-inventors received the 2020 Nobel Prize in Chemistry.[20] While Dr. Doudna and Dr. Charpentier's discovery stirred excitement about the endless possibilities this technology and its progeny may bring, their research also engendered accompanying fears of the unknown, fears which became a reality in 2018.

B. Controversy: The Ability of CRISPR to Change Humanity

At a science conference in China on November 26, 2018, Chinese researcher He Jiankui announced the birth of the world's first gene-edited babies.[21] Jiankui publicly stated that he had used CRISPR to make twin girls resistant to HIV infection by editing their embryos to be HIV-resistant prior to in vitro fertilization.[22] The researcher admitted to recruiting couples comprised of an HIV-positive father and an HIV-negative mother, who then jointly consented to the implantation of genetically engineered embryos. Jiankui was largely condemned for his decision to edit the twin girls' germline due to the medical uncertainties the girls may face, the permanence of germline editing, the unified global stance that CRISPR is inchoate and therefore not ready for human trials, and the fact that other far less invasive precautions could have prevented the babies from contracting HIV.[23]

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16 *Id.*

17 *See id.*

18 Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCI. 816, 816, 819–20 (2012).

19 *Id.* at 816, 820.

20 Heidi Ledford & Ewen Callaway, *Pioneers of CRISPR Gene Editing Win Chemistry Nobel*, 56 NATURE 346, 346 (2020).

21 Dennis Normile, *Researchers Who Created CRISPR Twins Defends His Work but Leaves Many Questions Unanswered*, SCIENCE (Nov. 28, 2018), https://www.science.org/content/article/researcher-who-created-crispr-twins-defends-his-work-leaves-many-questions-unanswered.

22 *Id.*

23 Dena Davis, *CRISPR in China: Why Did the Parents Give Consent*?, THE HASTINGS CTR. (Dec. 7, 2018), https://www.thehastingscenter.org/crispr-china-parents-give-consent/?gclid=Cj0KCQiAtICdBhCLARIsALUBFcEuXZXvU1Qx_e_0o5edaYwX5hhIFL25fgu5hx9TaWD_7nZNnZN4igMaAnhvEALw_wcB.

A Chinese court found that Jiankui and his colleagues were guilty of violating national regulations on biomedical research and medical ethics for their unauthorized use of restricted technologies and for falsifying information, which resulted in fraudulently obtained ethical permission for clinical research.[24] In 2019, the scientists were fined and sentenced to three years in prison.[25] The Chinese government responded to this situation by prompting research institutions across the nation to be more stringent with scientific ethics training, auditing, and enforcement, and they created the National Science and Technology Ethics Committee to uniformly evaluate and create ethics regulations across scientific fields.[26] It is believed that Jiankui was able to conduct his experiments on human subjects as a result of regulatory uncertainties in China and a lack of oversight from research review boards.[27]

In response to this event, in 2019 sixty-two individual scientists (practicing in the fields of biotechnology and bioethics) sent a letter to the U.S. Department of Health and Human Services calling for a global moratorium on germline gene editing.[28] Among those supporting this global ban on "CRISPR babies" were prominent international scientists and bioethicists, as well as the National Institutes of Health (NIH).[29]

There is a delicate balance effectuated between too much government interference in breakthrough science and the ability for necessary research and experimentation to safely occur. How do we adequately protect the interests of society at large, while enabling flexible ethical and scientific standards that promote research while also dissuading unethical practices? That is the question that many nations are now forced to consider.

II. REGULATORY ISSUES WITH CRISPR IN THE UNITED STATES AND ABROAD

A single country's unilateral decision to openly permit radical human genome

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24 *Id.*

25 Dennis Normile, *Chinese Scientist Who Produced Genetically Altered Babies Sentenced to 3 Years in Jail*, SCIENCE (Dec. 30, 2019), https://www.science.org/content/article/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail#:~:text=He%20Jiankui%2C%20the%20Chinese%20researcher,to%203%20years%20in%20prison.

26 *Id.*

27 *Id.*

28 Francis S. Collins, *NIH Supports International Moratorium on Clinical Application of Germline Editing*, NAT'L INSTS. OF HEALTH (Mar. 13, 2019), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-supports-international-moratorium-clinical-application-germline-editing.

29 *Id.*

editing could cause global uproar in the scientific community, similar to the response to He Jiankui's proclamation regarding the first born "CRISPR babies." Just as with climate change negotiations, an international consensus on ethical use and guidelines must be agreed upon for embryonic germline gene editing.

The 1964 Declaration of Helsinki, created by the World Medical Association, provided global ethical guidelines for research practices involving human subjects.[30] The United States required that the FDA mandate foreign clinical studies supporting drug applications to comply with the Declaration until 2007, when the United States replaced those international standards with the Good Clinical Practice guidelines (ICH-GCP).[31] The ICH-GCP standards are followed by the European Union, the United States, Australia, Canada, and Japan as member nations adhering to the internationally accepted standard for clinical trials, while numerous other nations choose to observe the regulations as well.[32] These ethical guidelines, with origins in the Declaration of Helsinki, provide unifying clinical practice specifications for studies involving human trials.[33]

If one country were to completely relax human germline gene editing oversight, it would likely create travel and research hubs for practices considered unconscionable across border lines. Discouraging this result is the very purpose for international standards such as the ICH-GCP.[34] Global agreement is the first step necessary for American adoption of embryonic germline editing practices. In early March 2023, a global forum, coined the "International Summit on Human Genome Editing," convened in London to moderate a global discussion on modern applications of CRISPR-Cas9.[35] The conference consensus on germline gene editing was that non-reproductive research on embryos and embryonic stem cells should continue, while research on heritable germline gene editing for reproductive purposes should remain prohibited as it has not yet been shown to meet reasonable standards of safety and efficacy.[36]

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30 *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS'N (June 1964, amended Oct. 2013), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.

31 *Good Clinical Practice*, INT'L SOC'Y OF NEPHROLOGY, https://www.theisn.org/in-action/research/clinical-trials-isn-act/isn-act-toolkit/study-stage-iii-conducting-a-trial/good-clinical-practice/#ich-gcp-principles.

32 *Id.*

33 *Id.*

34 *See id.*

35 *Third International Summit on Human Genome Editing*, THE ROYAL SOC'Y (2023), https://royalsociety.org/science-events-and-lectures/2023/03/2023-human-genome-editing-summit/.

36 *Statement from the Organising Committee of the Third International Summit on Human Genome Editing*, THE ROYAL SOC'Y (Mar. 8, 2023), https://royalsociety.org/news/2023/03/statement-third-international-summit-human-genome-editing/.

A. Current United States Regulations on CRISPR

In the United States, there are clear regulatory and statutory gaps in this area of reproductive medicine, for both scientific investment and oversight of researchers who may ethically overreach. In 1996, Congress passed an annual appropriations amendment called the "Dickey Wicker Amendment." This amendment prohibits the use of federal funds in support of "research in which a human embryo or embryos are destroyed, discarded, or knowingly subject to risk of injury or death greater than that allowed for research on fetuses in utero."[37] The amendment has been included and approved in yearly appropriations by Congress for 27 years.[38] The NIH issued a statement in 2015 regarding its firm stance that as a principal federal agency supporting and conducting medical research, they will not fund any use of gene-editing technologies in human embryos.[39] Furthermore, the NIH reiterated that its guidelines state that the Recombinant DNA Advisory Committee "will not at present entertain proposals for germline alteration."[40]

Beyond funding, in a capitalist society inventors and innovators want to reap financial benefit for the work they have created. This requires obtaining patent protection through the United States Patent and Trademark Office (USPTO) and other nations' patent offices, and to operate in America, clearance for human trials through the FDA.[41] As of 2021, there are over 6,000 CRISPR patents and patent applications with the USPTO alone, with approximately 200 added each month.[42] While the patent office looks at factors such as an inventor's disclosure and the novelty, utility, subject matter, and non-obviousness of an invention, it does not sentinel commercialization and freedom to use the claimed invention. This is where the FDA comes in.

The FDA has issued guidance for applicants developing human gene therapy products that utilize somatic cell modification, beginning with an Investigational New Drug Application to assess safety and efficacy of the human genome

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37 Megan Kearl, *Dickey-Wicker Amendment, 1996*, THE EMBRYO PROJ. ENCYCLOPEDIA, https://embryo.asu.edu/pages/dickey-wicker-amendment-1996 (Aug. 27, 2010).

38 *Id.*

39 *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NAT'L INSTS. OF HEALTH (Apr. 28, 2015), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos.

40 *Id.*

41 *See* 35 U.S.C. § 154; *Conducting Clinical Trials*, FDA, https://www.fda.gov/drugs/development-approval-process-drugs/conducting-clinical-trials (June 30, 2020).

42 *Patents on Genome Editing in Canada*, CBAN 2 (Mar. 3, 2022), https://cban.ca/wp-content/uploads/Patents-on-Genome-Editing-cban-March-2022.pdf.

editing product.[43] The FDA approved the first of such applications in 2021, permitting human trials for the genetic correction of a beta-globin gene responsible for sickle cell disease.[44] However, provisions specifically targeting human embryonic germline gene editing have been included in Congressional Annual Appropriations spending bills since 2016, serving as a de facto American ban on germline gene editing.[45] The FDA rider to the spending bill reads in part that the FDA is prohibited from considering requests to approve clinical trials "in which a human embryo is intentionally created or modified to include a heritable genetic modification."[46]

Despite the appropriation bill's language, there is a disturbing loophole in the American regulatory scheme regarding human germline gene editing: private funding. There is currently no federal legislation that restricts human genome editing *without* the use of federal funds.[47] The American regulatory system is reliant on trust. The system trusts that scientists do not want international criticism for impetuous actions, and also trusts that with scientific research comes the desire to exploit it for pecuniary gain through intellectual property protection.

B. Comparative Analysis of Foreign Regulatory Trends

In a survey of ninety-six nations, not a single country explicitly permits germline gene editing for reproductive purposes.[48] Five countries (Colombia, Panama, Belgium, Italy, and the United Arab Emirates) have policy prohibitions with potential exceptions for human heritable genome editing that allow for general therapeutic use, and Panama specifically allows use for the "elimination or reduction of a genetic defect or serious illness."[49] However, the numbers change when genomic modification is not intended for intrauterine pregnancy. Only forty out of the ninety-six countries surveyed have policies that address germline gene editing not intended for reproductive purposes.[50] While there is great regulatory and oversight policy variation for germline gene editing

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43 21 C.F.R. § 312.22(a) (2023).

44 Robert Sanders, *FDA Approves First Test of CRISPR to Correct Genetic Defect Causing Sickle Cell Disease*, BERKLEY (Mar. 30, 2021), https://news.berkeley.edu/2021/03/30/fda-approves-first-test-of-crispr-to-correct-genetic-defect-causing-sickle-cell-disease/.

45 Jocelyn Kaiser, *Update: House Spending Panel Restores U.S. Ban on Gene-Edited Babies*, SCIENCE (June 4, 2019), https://www.science.org/content/article/update-house-spending-panel-restores-us-ban-gene-edited-babies.

46 *Id.*

47 *See id.*

48 Baylis, *supra* note 12, at 369.

49 *Id* at 370–71.

50 *Id.* at 372.

globally, the one consistency is that, so far, not one nation has outright allowed it. Without the adoption of a global moratorium, what is there to stop any nation from being the first?

In a movement toward more radical reproductive intervention, in 2015 the United Kingdom became the first country to pass legislation permitting "three-person embryos."[51] The procedure, which is now legal in both the United Kingdom and Australia, combines the DNA of three people, two women and one man, to prevent the passage of metabolic diseases from mother to offspring.[52] Similar to germline gene editing in embryos, three-party embryos possess some of the same controversies medically, legally, and ethically, yet the two nations have gone forward with legalizing this mitochondrial treatment option. While the United States has not followed the regulatory direction of Australia or the United Kingdom yet, a fertility specialist employed by New Hope Fertility Center in New York City made a surprising announcement in 2016.[53] Dr. John Zhang reported the first live birth of a three-person baby after performing the controversial IVF technique in Mexico to avoid American regulatory oversight.[54]

C. The Push for the United States to Adopt Progressive Reproductive Medicine Techniques

The lesson taken from Dr. Zhang's report is that when other nations allow procedures that the United States does not, scientists will travel to perform operations and then return to allow the results to come to fruition in the United States.[55] American legislators can observe and learn from the steps taken in Australia's Mitochondrial Law Reform Bill of 2022 ("Maeve's Law") and the United Kingdom's Human Fertilisation and Embryology Act (2008).[56] While neither of these acts authorize CRISPR in human germlines, they do provide an

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51 James Gallagher, *UK Approves Three-Person Babies*, BBC NEWS (Feb. 24, 2015), https://www.bbc.com/news/health-31594856.

52 Lisa Rapaport, *Three-Parent IVF Now Legal in Two Countries*, MDEDGE (May 6, 2022), https://medauth2.mdedge.com/obgyn/article/254419/reproductive-endocrinology/three-parent-ivf-now-legal-two-countries.

53 Jennifer Couzin-Frankel, *Unanswered Questions Surround Baby Born to Three Parents*, SCIENCE (Sept. 27, 2016), https://www.science.org/content/article/unanswered-questions-surround-baby-born-three-parents.

54 *Id.*

55 *Id.*

56 Human Fertilisation and Embryology Act 2008 § 3, 22 U.K. Gen. Acts 1, 3 (amending Human Fertilisation and Embryology Act 1990); *see generally Mitochondrial Donation Law Reform (Maeve's Law) Act* 2022 (Austl.) (an Act to amend the law relating to human cloning and research involving human embryos, and for related purposes).

example of how large nations are adapting to modern reproductive technology and medical insight.[57]

Future CRISPR legislation in America must be narrow (only applicable to certain well-studied gene mutations) and must require thorough longitudinal reporting mechanisms between ethical boards, administrative oversight, and bio-medical scientists, geneticists, and physicians conducting experimentation. Ultimately, it is requisite for global consensus on germline gene editing practices before the United States codifies statutes and regulations on CRISPR for this application. As previously discussed, in the United States currently there are no federal penal laws, civil penalties, or clear guidance on the use of CRISPR for embryonic germline gene editing if research is privately funded. Reliance on trust is becoming increasingly insufficient.

If the U.S. were to take major strides toward regulating this technology for germline applications, the first step would be to delimit permissible or illegal experimentation, regardless of public or private funding. Subsequently, legislators would be required to redact language prohibiting the use of federal funding for embryonic modification research (such as through the NIH rider), as well as the FDA ban on considering clinical trial applications in this area (such as what the Democrat-led spending panel in the U.S. House of Representatives attempted to do in 2019).[58] Without the FDA rider ban, Congress frees the FDA to consider clinical trial applications for germline gene editing in embryos, which will likely occur before federal funds are allocated to germline gene editing research. This congressional action alone would open the door to the first legal intrauterine pregnancy with CRISPR embryos (notwithstanding the FDA bar on considering clinical trial applications for embryonic genome editing).

Government action is only one facet of this dispute. CRISPR embryos become babies, who grow and mature and have their own children. Who then has the authority to provide consent on behalf of an entire familial line, and whose "yes" are we compromising later for assent granted now? Even if permission is granted based on informed consent, is that consent even valid without grasping the full scope of potential risks that are currently unknown?

III. MATERNAL AND FETAL AUTONOMY

The United States Constitution protects against the unjust abridgement of individual rights from the overreach of a State:

> No State shall make or enforce any law which shall abridge the

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57 *Id.*

58 Jocelyn Kaiser, *House Spending Panel Drops U.S. Ban on Gene-Edited Babies*, STAN. L. SCH. (May 24, 2019), https://law.stanford.edu/press/house-spending-panel-drops-u-s-ban-on-gene-edited-babies/.

> privileges or immunities of citizens of the United States; nor shall any State deprive any *person* of life, liberty, or property, without due process of law; nor deny to any *person* within its jurisdiction the equal protection of the laws.[59]

Through precedential case law, the Supreme Court has held that an individual has constitutionally protected privileges to bodily integrity, to procreation, and to direct the upbringing of their children.[60] Parental decisions, of course, begin prior to the birth of a child. One of the first choices made during pregnancy/pre-conception (focusing primarily on a mother) is deciding on health care providers for fertility, prenatal care, or abortion services. Healthcare practitioners require informed consent from a pregnant mother every time she undergoes an examination or procedure during pregnancy, a doctrine "firmly entrenched in American tort law."[61] When providing informed consent for medical decisions, a mother, and parents collectively, assert autonomy over their own bodies and health, as well as the prenatal health of the fetus they are carrying.

During pregnancy, a mother and the child that she is carrying are in perfect symbiosis, functioning as one organism. There are many components of pregnancy and prenatal care that a pregnant mother has agency over (notwithstanding the legal rights of the child's other parent). When two people are bound for nearly a year, and the personal and medical decisions of the mother directly affect the development and health of the fetus, fetal rights may be asserted to halt or compel the mother's actions.[62] This is the result of the long-held ability for the state to intercede in parental decision-making where a child's welfare is at risk.[63] When the opinions of a medical practitioner and a pregnant mother about a course of treatment conflict, judicial intervention may be sought out for resolution. The following state and federal court decisions illustrate instances where a judicial order has supplanted parental wishes, the factors in determining whose autonomy prevails, and the legal status of embryos. While there are conflicting cases and views of public policy across the United States affecting each of these issues, the following examples allow for predictions of how pre-implantation embryos may be viewed in light of CRISPR-Cas9 and human germline gene editing.

The following constitutional questions will need to be considered if this technology becomes a mainstream medical reality through these decisions: 1) at what gestational mark do courts grant a fetus assertable fetal autonomy over that

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59 U.S. CONST. amend. XIV § 1 (emphasis added).

60 *See* Meyer v. Nebraska, 262 U.S. 390, 399 (1923); Pierce v. Soc'y of Sisters, 268 U.S. 510, 535 (1925); Troxel v. Granville, 530 U.S. 57, 66 (2000).

61 Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990).

62 *See, e.g.*, cases cited *supra* note 61.

63 *See, e.g., id.*

of their parent(s)? 2) can a court hold that an individual possesses embryonic constitutional rights pre-implantation? 3) what place and weight does generational autonomy hold in this situation? 4) when and to what extent can a state or federal government interfere with prenatal/pre-conception decisions regarding medical screening and treatment under the justification of legitimate and compelling government interests?

A. Maternal Medicine and Prenatal Care

1. Blood Transfusions

In 1985, a pregnant patient was admitted to a hospital after eighteen weeks' gestation following a car accident and subsequently refused a blood transfusion on religious grounds.[64] Upon a finding that the patient was in critical condition and that the fetus was in "mortal danger," a New York court appointed a *parens patriae* for the fetus who ordered that a blood transfusion be compelled.[65] The court reasoned that, "the State has a highly significant interest in protecting the life of a mid-term fetus, which outweighs the patient's right to refuse a blood transfusion on religious grounds."[66]

2. HIV Medication

The Division of Youth and Family Services brought an action against a mother in the state of New Jersey, in which they alleged a violation of a state child abuse and neglect statute.[67] The mother knew during her pregnancy that she was HIV positive and had been prescribed antiretroviral therapy to reduce the chance that the virus would be passed on to her developing fetus.[68] The mother refused to ingest the medication.[69] Upon evaluation of the facts, the court held that a woman has a constitutionally protected right to her body during pregnancy, even to the extent that she is able to refuse medical treatment when such refusal may increase her risk of, or directly cause, termination of the pregnancy.[70]

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64 *In re* Jamaica Hosp., 491 N.Y.S.2d 898, 899 (Sup. Ct. 1985).
65 *Id.*at 899–900.
66 *Id.* at 900.
67 N.J. Div. of Youth and Fam. Servs. v. L.V., 889 A.2d 1153, 1154 (N.J. Super. Ct. Ch. Div. 2005).
68 *Id.* at 1155.
69 *Id.*
70 *Id.*

3. Drug and Alcohol Use During Pregnancy

In the United States, twenty-five states, as well as the District of Columbia, consider substance use during pregnancy to be child abuse under civil-welfare statutes, due to the numerous potential ill-effects of drugs and alcohol on a developing fetus.[71] The highest courts in both South Carolina and Alabama have affirmed child abuse convictions of mothers for prenatal substance abuse.[72] Such laws can result in the termination of parental rights and criminal convictions, even if substance abuse or addiction occurred prior to the birth of the fetus.[73] Currently, in Wisconsin, South Dakota, and Minnesota, substance abuse during pregnancy is grounds for civil commitment.[74] In Wisconsin, approximately 400 pregnant women each year are investigated for "unborn child abuse" under the state's child abuse statute.[75] Upon medical screening showing that a mother is using drugs, Wisconsin mothers may be forced into treatment centers or jail for the duration of their pregnancy.[76]

In addition to drug use for recreational purposes, there is also a potential conflict of rights raised by prescribed pharmaceutical drug use during pregnancy, such as with pregnant mothers diagnosed with cancer. In this scenario, a woman must consider her health against the option of delaying chemotherapy/radiation until after the baby is born, because many cancer treatments have teratogens that are harmful to fetal development.[77]

4. Involuntary Cesarean Section

Upon medical assessment, it was determined by an examining physician that a pregnant mother with a viable fetus at thirty-nine weeks' gestation had complete placenta previa and the unborn child would not survive vaginal

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71 *Substance Use During Pregnancy*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/substance-use-during-pregnancy (last visited Dec. 14, 2023).

72 *See* Whitner v. State, 492 S.E.2d 777, 784 (S.C. 1997); Ankrom v. State, 152 So. 3d 373, 385 (Ala. Crim. App. 2011).

73 *See Whitner*, 492 S.E.2d at 778–79; *see also Ankrom*, 152 So. 3d at 375–76.

74 Phoebe Petrovic, *Policing Pregnancy: Wisconsin's 'Fetal Protection' Law Forces Women into Treatment or Jail*, PBS WIS. (Dec. 14, 2022), https://pbswisconsin.org/news-item/policing-pregnancy-wisconsins-fetal-protection-law-forces-women-into-treatment-or-jail/#:~:text=Wisconsin%20is%20one%20of%20just%20five%20states%20that%20allow%20civil,for%20the%20person%20gestating%20it.

75 *Id.* (citing WIS. STAT. § 48.981 (2023)).

76 *Id.*

77 *See Cancer During Pregnancy*, AM. CANCER SOC'Y, https://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/cancer-during-pregnancy.html (last visited Nov. 16, 2023).

delivery, resulting in medical recommendation that the mother undergo a caesarian section.[78] The parents of the child opposed the surgical delivery as against their religious beliefs.[79] Due to the exigency of the matter, the trial court in Georgia awarded the State temporary custody of the unborn child and ordered that the mother be compelled to have a caesarian section upon a petition by the Department of Family and Children's Services alleging that the child was "deprived . . . without proper parental care necessary for his or her physical health," in violation of state statute.[80]

5. Issue of Informed Consent in Elective Procedures for Maternal Decision-Making

Judicial decisions that seek to protect a developing life have an element of understandability, because states are delegated police power from the federal government to regulate and enforce public health and welfare laws protecting all citizens within the individual states. Even more innocuous than judicial interference in prenatal care however, is the practice of routinizing elective genetic testing, induction, and cesarean section procedures where women willingly agree to medical interventions without truly informed consent.[81] In this context, informed consent means a full understanding of risks and alternative options, including the option to refuse treatment. Historically, genetic testing has been used in high-risk pregnancies, in geriatric pregnancies, in families with known heritable genetic diseases, and for women that have had previous pregnancies affected by certain conditions.[82] However, these types of noninvasive tests are becoming so commonplace in American obstetrics that pregnant mothers are, in many cases, not being provided with the opportunity to give informed consent.[83] There are trends already showing how genetic testing is influencing maternal decision-making, particularly in electing for an abortion.[84]

B. Fetal Personhood

Much of the constitutional debate surrounding abortion rights focuses on the

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78 Jefferson v. Griffin Spalding Cnty. Hosp. Auth., 274 S.E.2d. 457, 458 (Ga. 1981).
79 *Id.*
80 *Id.*
81 Lindsey Parham et al., *Expanding Use of cfDNA Screening in Pregnancy: Current and Emerging Ethical, Legal and Social Issues*, 5 CURR. GENET. MED. REP. 44, 44–46 (2017).
82 *Id.*
83 *See id.*
84 *Id.*

Fourteenth Amendment and to what extent an unborn fetus fits into the constitutional framework of a "citizen" or a "person" for purposes of cognizable legal rights.[85] Upon state recognition of fetal personhood, a woman's agency over her body is vastly limited, as nascent human life legitimizes a state's intervening actions to protect that life.

In 1973, the Supreme Court of the United States held that a fetus has a constitutionally held right to life if they are deemed "viable," which was determined to be around twenty-four to twenty-eight weeks' gestation.[86] While *Roe v. Wade* regarded a federal guarantee, lasting through 2022, to obtain an abortion up until fetal viability, it also contemplated when a court will deem that a fetus is a legally recognizable person.[87] The Court stated in its opinion that as a woman approaches full term (commonly regarded as thirty-nine weeks' gestation) and passes the viability point in pregnancy, the state's important and legitimate interests in protecting fetal life become "compelling."[88]

With the overturn of *Roe v. Wade*, states are permitted to adopt their own legislation on when policymakers view the beginning of life.[89] An individual state's legislation now determines where and if a pregnant woman can have a legal abortion in that state.[90] Anti-abortion legislation has sprouted up across the United States with an emergence of bill proposals attempting to outright ban the procedure, or to grossly limit access by effectuating "heartbeat bills."[91] These bills seek to prevent abortion after cardiac activity is observed with a fetal heartbeat detector, usually seen around six weeks' gestation.[92] Along with heartbeat bills, there has also been an emergence of new fetal personhood legislation that seeks to statutorily establish that personhood and fundamental rights attach at the moment of conception.[93] Definitions seen in proposed state legislation to criminalize abortions classify an "unborn child" not by measures of viability, but rather by meaning the *moment of conception* through birth.[94]

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85 *See* Roe v. Wade, 410 U.S. 113, 156–57 (1973); Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 859–61 (1992); Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2251–52 (2022).

86 *Roe*, 410 U.S. at 163–64.

87 *See id.* at 160–62.

88 *Id.* at 125, 163–64.

89 *Dobbs*, 142 S. Ct. 2228 (2022).

90 *See id.* at 2243.

91 Julie Carr Smyth, *Explainer: Abortion Landscape Under State 'Heartbeat' Laws*, AP NEWS (June 29, 2022, 5:11 PM), https://apnews.com/article/abortion-us-supreme-court-health-ohio-tennessee-0056dcfb4e5fe1590f07b5993c52078a.

92 *Id.*

93 *See, e.g.*, MO. REV. STAT. § 1.205 (2023); ALA. CODE § 13A-6-1 (2023); KAN. STAT. ANN. § 65-6709 (2023); GA. CODE ANN. § 31-9A-2 (2023); ARIZ. REV. STAT. ANN. § 36-2151 (2021).

94 *See* state statutes cited *supra* note 94.

Beginning in 2019, the state of Georgia permitted pregnant mothers to claim their unborn children as dependents on their tax returns with a personal tax exemption of $3,000 per fetus.[95] The Georgia Department of Revenue provided the following caveat: the fetus being claimed must have a detectable heartbeat.[96] This legislation illustrates the equal recognition of personhood for both born and unborn children under the state tax code.[97] At the federal level, anti-abortion measures are being raised in both chambers of Congress with bill proposals such as the "Life at Conception Act."[98] The primary purpose of this legislation is to grant equal protection rights under the Constitution for the "right to life of each born *and preborn human person.*"[99] Further alluding to a recognition of fetal personhood, regardless of vague lines of viability and nonviability, there have been instances where individuals post-birth are able to sue tortfeasors for deformities that were imposed on them prenatally. The Supreme Court of New Jersey has held:

> [J]ustice requires that the principle be recognized that a child has a legal right to begin life with a sound mind and body. If the wrongful conduct of another interferes with that right, and it can be established by competent proof that there is a *causal connection* between the wrongful interference and the harm suffered by the child when born, damages for such harm should be recoverable by the child.[100]

According to this stance of considering viability at the time of the injury, if a viable fetus sustained causal harm in utero, then after birth they should be given the same opportunity for redress, as if the harm had occurred after birth.[101]

In recent years, the United States has seen the enhanced recognition of fetal personhood in tort, criminal, and constitutional law.[102] According to *Dobbs v. Jackson Women's Health*,

> The Constitution makes no reference to abortion, and no such right is implicitly protected by any constitutional provision, including the one on which the defenders of *Roe* and *Casey* now chiefly rely—the Due Process Clause of the Fourteenth Amendment. That provision

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95 Sharon Bernstein, *Georgia Anti-Abortion Law Allows Tax Deductions for Fetuses*, REUTERS (Aug. 2, 2022, 7:32 PM), https://www.reuters.com/world/us/georgia-anti-abortion-law-allows-tax-deductions-fetuses-2022-08-02/.

96 *Id.*

97 *Id.*

98 Jamie Bittner, *'Life at Conception' Act Reintroduced in Congress as Republicans Control the House*, GRAY DC (Jan. 25, 2023, 3:56 PM), https://www.graydc.com/2023/01/25/life-conception-act-reintroduced-congress-republicans-control-house/.

99 *Id.* (emphasis added).

100 Smith v. Brennan, 157 A.2d 497, 503 (N.J. 1960) (alteration in original) (emphasis added).

101 *See id.*

102 *See, e.g.*, Bernstein, *supra* note 96.

> has been held to guarantee some rights that are not mentioned in the Constitution, but any such right must be "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty.[103]

What this statement implicitly touches on is the definition of a "person" for the purposes of the Constitution. Under *Dobbs*, recognition of life begins when states, authorized by the Tenth Amendment, say it begins. Prior to 1972, there was no federal recognition of a right to an abortion, and prior to 1960, contraception was not even brought to the market.[104] Following Justice Alito's majority opinion, a right to life upon conception has been "deeply rooted in this Nation's history."[105] In the absence of other federal action, the unborn are arguably persons for the purpose of the Fourteenth Amendment, therefore possessing assertable substantive due process rights.

The United States is now following a trend where current state action is weakening maternal autonomy, while strengthening fetal autonomy. In the past, state intrusion into a woman's privacy and her ability to parent was justified by situations causing extreme harm or the imminent potential for harm to the developing fetus.[106] Presently however, fetal personhood is actually becoming embryonic personhood. As defined by the Cleveland Clinic, an embryo is the term used to describe the period between conception through the eighth week of gestation, whereas a fetus is the term used from week nine through birth.[107]

IV. EMBRYONIC PERSONHOOD

The preceding commentary argued that a fetus, and in certain scenarios an embryo, is provided with assertable constitutional rights in instances where a state seeks to protect that life under the current legal framework set forth by the Supreme Court. This limits maternal autonomy over the right to privacy, the right to medical decision-making, and the right to bodily integrity. As it stands, abortion legislation aimed at pregnancies under eight weeks assumes that the embryo is implanted into the mother's uterus.[108] But what about preimplantation

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103 Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2242 (2022).

104 *See. e.g.*, Griswold v. Connecticut, 381 U.S. 479, 481–82 (1965) (holding that taking contraception to prevent pregnancy is a fundamental right falling within the 'penumbra' of rights implicit in the Fourth Amendment's right to privacy, incorporated in the Fourteenth Amendment's Due Process Clause).

105 *Dobbs*, 142 S. Ct. at 2242 (2022) (citing Washington v. Glucksberg, 521 U.S. 702, 721 (1997)).

106 *See In re* Jamaica Hosp., 491 N.Y.S.2d 898, 899 (Sup. Ct. 1985).

107 *Fetal Development*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/articles/7247-fetal-development-stages-of-growth (Mar. 3, 2023).

108 *See, e.g.*, Bernstein, *supra* note 96.

embryos ("pre-embryos")?

A. Embryos and Their Nebulous Legal Classification

Generally, when intended parents freeze embryos, it is encouraged that they have a preimplantation embryo disposition agreement stating what is to happen to the embryos in the instance of divorce, death, or a biological parent's desire to divest themselves of parental responsibility.[109] These contracts function like custody agreements implemented for children when two parents are no longer together. Under these agreements, are pre-implantation embryos personal property or people?

In a divorce settlement, the Supreme Court of Tennessee held that "pre-embryos are not, strictly speaking, either 'persons' or 'property,' but occupy an *interim category* that entitles them to special respect because of their potential for human life."[110] However, other state courts have held that frozen pre-embryos are marital property subject to distribution in divorce cases, classifying them as more akin to property versus a person.[111] There is an element of incongruity between the treatment of human embryos as personal property—particularly where there is a great potential of life upon implantation—and their treatment as a person because an embryo in isolation is not functionally equivalent to a viable fetus.

This incongruity has been reflected in case law where courts have declined to appoint a guardian ad litem for embryos because "embryos are not persons with legally protectable interests."[112] Recently, when plaintiffs sought to enjoin the NIH from implementing guidelines consistent with President Barack Obama's 2009 executive order that removed limitations on research and access to federal funding for human embryonic stem cells,[113] as the guidelines posed a risk of imminent injury (i.e., embryonic destruction), the court held that the embryos lacked standing to bring a cause of action in federal court because they are not persons under the law.[114]

As fetal personhood legislation gets stronger, the moment of conception, even if it occurs in a laboratory, may be implicated and controlled by these laws. No longer would a pre-embryo be considered quasi-personal property lacking legal

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109 *Cf*. Jocelyn P. v. Joshua P., 2023 Md. App. LEXIS 592, *8 (App. Ct. Sept. 6, 2023) (holding that trial courts must first assess the preference of progenitors that was reduced to writing, or orally agreed upon, prior to any other balancing test for the disposition of cryogenically frozen embryos).

110 Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992) (emphasis added).

111 McQueen v. Gadberry, 507 S.W.3d 127, 132 (Mo. Ct. App. 2016).

112 Doe v. Shalala, 862 F. Supp. 1421, 1426 (D. Md. 1994).

113 Exec. Order No. 13505, 74 F.R. 10667 (2009).

114 Sherely v. Sebelius, 686 F. Supp. 2d 1, 6 (D.D.C. 2009).

standing (making their "non-person" classification far more conducive to more invasive research), rather they would likely eventually be deemed unborn persons under the United States Constitution. The largest impact of this result would be on embryonic stem cell research. Human embryonic stem cells are pluripotent, which allows them to develop into any cell type in the human body and they are capable of long-lasting proliferation.[115] The potential applications for these stem cells are enormous, and include possibilities for curing or treating blindness, Parkinson's disease, ALS, Alzheimer's disease, juvenile diabetes, and various other diseases.[116] Stem cells are derived from the inner cell mass of a blastocyst (an embryo at approximately five to six days after fertilization), which results in destruction of the un-implanted embryo.[117]

Should fetal personhood legislation gain traction, particularly with codification at the federal level, embryonic stem cell research would stop. Furthermore, as it stands, scientists are only able to culture and conduct research on in vitro embryos for two weeks (known as the fourteen-day rule) after fertilization.[118] This brief period respects the potential for life and places firm parameters on experimentation (although there is a modern push to extend the fourteen-day rule to twenty-eight days).[119]

Despite the difference between implanted embryos and in vitro pre-embryos, they are one and the same in their nature of latency. If life is established upon conception, then life has surely begun in both scenarios. If this were the case, it would result in a finding that, yes, there would be embryonic constitutional rights pre-implantation.

B. CRISPR and Embryos

In 2017, it was reported that a team of American researchers out of Oregon Health and Science University (OHSU) used CRISPR to correct a gene mutation

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115 CHRISTINE VESTAL, THE SCIENCE BEHIND STEM CELL RESEARCH, PEW RSCH. CTR. (2008), https://www.pewresearch.org/religion/2008/07/17/the-science-behind-stem-cell-research/.

116 *Id.*

117 *Examining the Ethics of Embryonic Stem Cell Research*, HARVARD STEM CELL INST., https://hsci.harvard.edu/examining-ethics-embryonic-stem-cell-research#:~:text=Opponents%20argue%20that%20the%20research,taking%20of%20innocent%20human%20life.%E2%80%9D (last visited Dec. 14, 2023).

118 John B. Appleby & Annelien L. Bredenoord, *Should The 14-day Rule For Embryo Research Become the 28-Day Rule?*, EMBO (Aug. 7, 2018), https://www.embopress.org/doi/full/10.15252/emmm.201809437#:~:text=The%2014th%20day%20is,any%20further%20research%20on%20embryos.

119 *Id.*

called "MYBPC3" that is linked to heritable cardiac conditions.[120] Unlike the embryos edited and implanted by He Jiankui in China, the embryo was never implanted, but the team reported incredible results: of the zygotes, 72 percent safely corrected the MYBPC3 gene.[121] The OHSU case was the first reported human germline editing conducted in the United States.[122] Similarly, researchers at Columbia University have used CRISPR in an attempt to correct genes causing an inheritable form of blindness, retinitis pigmentosa.[123] So far, these edited embryos have never surpassed a few days in a laboratory in the United States and have not resulted in a live birth.[124]

These experiments are not likely to stop, and as other nations begin to relax their own regulatory schemes to permit human trials with gene-edited embryos, the United States will follow suit. There is an enormous possibility to extinguish human suffering resulting from congenital diseases that could be prevented, but of course there are also ethical, moral, and legal implications.[125] When an entire genetic line is permanently affected by this technology, is it adequate that a parent contributing a gamete to the embryo consent to genetic modification? Can the government mandate genetic screening and genetic intervention in high-risk individuals?

C. Post-*Roe* and the Rise of the Embryo as a "Person"

It has long been recognized that constitutional protections do not mature when an individual reaches the age of majority, because the individual possesses the same protections as a child, but there may be more state discretion in regulating the activities of a child versus an adult.[126] The Supreme Court has utilized a three-factor test when assessing the validity of a state intrusion on a minor's constitutional rights: 1) the peculiar vulnerabilities of children; 2) a child's inability to make critical decisions in an informed, mature manner; and 3) the importance of a parent's role in rearing their child.[127] Embryos are not children, but many will be and, consequently, many will also be adults. This working

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120 Jacqueline Howard, *Scientists Edit Disease-Causing Gene Mutation in Human Embryos*, CNN HEALTH, https://www.cnn.com/2017/08/02/health/crispr-human-embryos-gene-editing-study/index.html#:~:text=Scientists%20are%20getting%20one%20step, human%20embryos%20using%20the%20approach (Aug. 2, 2017).

121 *Id.*

122 *Id.*

123 *CRISPR Used to Repair Blindness-causing Genetic Defect in Patient-derived Stem Cells*, CUIMC (Jan. 27, 2016), https://www.cuimc.columbia.edu/news/crispr-used-repair-blindness-causing-genetic-defect-patient-derived-stem-cells.

124 *See id.*

125 *See infra* Part V.

126 Planned Parenthood v. Danforth, 428 U.S. 52, 74 (1976).

127 Bellotti v. Baird, 443 U.S. 622, 634 (1979).

framework is to analogize how federal courts interpret constitutional rights of individuals that do not yet have a societally realized voice for life-altering decision-making in a mature and educated manner.[128]

In modern America, embryonic personhood is becoming nationally pronounced. Can it truly be said that a parent's desire to rear a child without the encumbrance of a preventable condition (as valid as it may appear) constitutionally supersedes the embryo's rights to be free from permanent genetic intrusion, not only for themselves, but for their children, grandchildren, great-grandchildren and so on? The debate about the human genome and DNA sequences is not the same as phenotypic and sex selection implicated by the designer baby debate, although there is some overlap, which is discussed below; nor is it the same as pre-implantation genetic testing.[129] Implicit in Congress' hesitancy to federally support embryonic germline research is the consideration of generational autonomy. Not only would the allowance of this technology remove an individual's ability to grow and adapt in a biologically natural way, it would also result in a generation making decisions on behalf of the future of humanity. Decisions of one generation that affect another are commonplace, but the interposition of radical medical intervention possesses a newfound gravity.

The use of germline gene editing has the potential to move from a therapeutic intervention method to a widespread American public health measure. If certain severe conditions were known to be completely eradicated, or their prevalence greatly reduced, state action may demand compliance with mandatory genetic screening and intervention methods. If embryos are people under the Fourteenth Amendment, the mandatory use of CRISPR-Cas9 in this circumstance violates the Due Process Clause and Equal Protection Clause. Radical genetic intervention impinges the liberty interest of the individual, while also creating classes of people that have and have not been subject to genetic manipulation (potentially resulting in public/ government favoritism or animus).

The involuntary use of CRISPR very likely also implicates the Fourth Amendment where individuals, which would encompass embryos, would be subject to an unreasonable search and seizure of their person (their genome).[130] The Supreme Court has held that "a buccal swab on the inner tissues of a person's cheek in order to obtain DNA samples is a search [under the Fourth Amendment]."[131] Virtually any "intrusion into the human body" will work an

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128 *See id.*

129 *See* Birchfield v. North Dakota, 579 U.S. 438, 474 (2016) (holding that warrantless blood tests are intrusive and infringe on an individual's Fourth Amendment right to privacy and unless exigent circumstances require invasive bodily tests, less invasive means must be used).

130 *See, e.g., id.*

131 Maryland v. King, 569 U.S. 435, 446 (2013).

invasion of "'cherished personal security' that is subject to constitutional scrutiny."[132] It follows that genomic testing and profiling fit within that holding.

Additionally, there would eventually become two classes of people in society, those that have been subject to human germline gene editing and those who have not. Professor Lee Silver of Princeton University coined the term *GenRich* to describe a future class of individuals that have been genetically enriched versus a class of "naturals," individuals without genomic "fortification."[133] As the number of allowable applications for CRISPR increases, the division between individuals with access to this technology versus those that do not may become vast.

What is so staggering are the unknowns. Since research remains inchoate on germline embryonic editing, it is impossible to fully comprehend the longitudinal effects that result from the potential effects of the technology and the probable applications of CRISPR. There are known adverse effects that scientists are currently trying to circumvent and solve, such as off-target effects (which result in the unintended cleavage and mutation of untargeted genomic sites) and the occurrence of mosaic mutations (where more than one set of genetic information is found within the cell, and if they occur in the germline, then these mutations may be passed on to offspring).[134] Who then becomes responsible for undesirable genetic expressions that would not have resulted but for this medical intervention—parents garnering a medical practitioner with consent, the administering physician, or the federal government? Could an embryo gain legal standing to demand redress for these abnormalities, even when it never results in a live birth?

It may ensue that one known harm is supplanted for another unknown heteroclite expression, where the government provides initial clearance for the use of CRISPR and fervid parents readily authorize the procedure without being fully conscious of what their "yes" and signature are agreeing to. This act of parsing through biodiversity directly abridges individual liberty, without stringent regulation and carefully selective allowances.

V. PANDORA'S BOX

When you meet your child for the first time, you are awestruck by this miracle. This awe couples with hope and anxiety. A parent has an overwhelming hope to raise a person that is kind, open-minded, curious, and able to reach any

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[132] *Id.* (quoting Cupp v. Murphy, 412 U.S. 291, 295 (1973)).

[133] LEE M. SILVER, REMAKING EDEN 3 (2004), https://www.leemsilver.net/CNmedia/articles/EdenEpilogue.pdf.

[134] *See* Moog et al., *Disorders Caused by Genetic Mosaicism*, 117 DTSCH ARZTEBL INT. 119, 119 (2020) (Ger.), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7081367/.

dream he or she ventures to achieve. There is also a lingering wish that an uncertain world will be accepting of that child, no matter their appearance, mental or physical ability, ethnicity, gender, or any other potential challenge that could be faced.

Throughout human history, there has been a delicate balance between fear of radical technological and medical advancement, comfort in consistency, and an urgency for change. The paradox of introducing germline gene editing into mainstream medicine is that, when given the choice to take away hardships from your own child's life, love may trump reason. Is love enough if the release of the unknown and potential evils cannot be undone? These evils could include eugenics, a pursuit for transhumanism, and overreaching public policy that is capable of changing humanity entirely. Critics of CRISPR's use in germline gene editing warn of the potential for turpitude, while others worry that the current generation is infringing on the rights of individuals that do not yet exist.[135]

A. Eugenics and Transhumanism

CRISPR, at a surface level, may be deemed a method by which to "correct" genetic mishaps. When permitting human trials, policy makers must decide what traits and conditions are so unfavorable to an individual's happiness, quality of life, and potential while balancing other expenditures related to that pathology, such as government resources used, average hospital and medical costs, and costs of full-time or assisted care, to determine whether the condition warrants eradication.

Where exactly do we morally draw the line between what genetic expression is inadequate enough that as a society we would allow legislatures to permit its eradication? How far are we willing to go and what safeguards are required? When certain people are vested with the ability to decide to eliminate genetically "weak" expressions in society, it is uncertain what the definition of a qualifying disability will include.

As a result of vast prenatal screening technology in Iceland, a version of eugenics has already been seen amongst pregnant mothers in that country.[136] Nearly "100% of [Icelandic mothers] chose to abort [their] child" when genetic

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135 *See, e.g.*, Sandy Sufian & Rosemarie Garland-Thomson, *The Dark Side of CRISPR*, SCI. AM. (Feb. 16 2021), https://www.scientificamerican.com/article/the-dark-side-of-crispr/.

136 Ethan Morales, *Crispr and the Spectre of Eugenics*, BERKELEY POL. REV. (July 25, 2021), https://bpr.berkeley.edu/2021/07/25/crispr-and-the-spectre-of-eugenics/.

screening came back with a positive result for Trisomy 21.[137] As a result of this maternal decision, the incidence of Down Syndrome in the Icelandic population is close to zero.[138] The incidence of this condition amongst a population being nearly zero indicates a firm national attitude against allowing the birth of babies with a disability.[139] A decision amongst parents, notwithstanding the possibility that physicians in the country have pushed mothers toward abortion, has narrowed the diversity of the population.[140] If a nation feels so strongly about one disability, how about others not yet within their "control?" Iceland has been criticized for appearing to have an ableist mentality against children with disabilities, although they deny having this attitude.[141] Does the record speak for itself?

In addition to the number of instances CRISPR could be used in, another concern is the question of who CRISPR would be available to. The cost of CRISPR's application to germline gene editing is uncertain as it is not yet permitted. However, permissible CRISPR gene therapy carries a weighty price tag.[142] Treatment for sickle cell disease with CRISPR technology is reported to cost, on average, $2 million per patient.[143] Modern fertility services, such as IVF, range from $15,000 to $30,000 per cycle, with many mothers requiring numerous cycles prior to conception.[144] Logistically speaking, IVF is not an economically viable option for most people who have difficulty getting pregnant, even if health insurance is able to cover some of the medical costs.[145] CRISPR for germline gene editing would likely benefit only the wealthy who are capable of affording the treatment and, accordingly, would present another socioeconomic divide amongst the American population for individuals and families with limited financial means.

The survival of the fittest mentality then becomes less altruistic and far more about the wealthy having access to another social advantage. Currently, there are clinics across the United States that permit a parent to choose an embryo's gender and eye color.[146] Eye color, possible future height, and hair color are

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137 *Id.*

138 *Id.*

139 *See id.*

140 *Id.*

141 *Id.*

142 *Id.*

143 Ian Thomas, *How CRISPR Gene Editing Will Treat Diseases in Future: Nobel-Winning Intellia Co-Founder Jennifer Doudna*, CNBC EVOLVE, https://www.cnbc.com/2021/06/30/how-crispr-gene-editing-will-treat-disease-intellia-founder-doudna-.html (June 30, 2021, 10:17 AM).

144 Marissa Conrad, *How Much Does IVF Cost?*, FORBES, https://www.forbes.com/health/family/how-much-does-ivf-cost/ (Aug. 14, 2023, 7:04 AM).

145 *See id.*

146 THE FERTILITY INSTS., https://www.fertility-docs.com/ (last visited Dec. 14, 2023).

relatively trivial, superficial aspects of a person. Additionally, a majority of American IVF clinics perform pre-implantation genetic diagnosis to sort between healthy embryos and embryos suspected to have a genetic defect.[147] This practice results in the fertilization of an embryo that has made the genetic "cut." If society is already aptly willing to pick and choose between genetic traits and phenotypes, what would prevent a parent with the financial ability from enhancing intelligence?

Transhumanism seeks to use emerging medical technology to augment the human experience.[148] This entails an individual or the parents of a future child (the instance applicable to embryonic germline gene editing) consenting to "biological enhancement," including increased strength, immunity, memory, cognitive capacity, or expression of other "favorable" genetic expressions.[149] This biologically liberal view seeks to permit the use of gene splicing at will (whim?) and strives to take an active role in human evolution.[150] Augmenting human capacity to this extent is unlike any current necessary or elective procedure, burgeoning beyond the bounds of the traditional functions and goals of medicine.

In comparing the public's view of gene editing in embryos, a survey of American adults revealed that seventy-two percent stated that CRISPR's use for treating a serious condition or disease appearing at birth would be appropriate.[151] In contrast, only sixty percent approved of the use of this technology to reduce the risk of a serious disease that may occur over the course of the baby's lifetime, and, unsurprisingly, only nineteen percent agreed with the use of CRISPR for enhanced cognition purposes.[152]

B. Government Mandates and Involuntary Medical Disclosure

The three years between 2020—the start of the COVID-19 pandemic—and 2023, where a widespread return to normalcy makes masking and regular vaccinations feel like a not-so-distant remnant of the past, have presented a key example for how CRISPR-Cas9 could gain social acceptance. As a society we

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147 Susannah Baruch et al., *Genetic Testing of Embryos: Practices and Perspectives of US in Vitro Fertilization Clinics*, 89 FERTILITY & STERILITY 1053, 1055 (2008).

148 Mara Almeida & Robert Ranisch, *Beyond Safety: Mapping the Ethical Debate on Heritable Genome Editing Interventions*, 9 HUMAN. AND SOC. SCIS. COMMC'NS 1, 4–6 (2022).

149 *Id.* at 4–7.

150 *Id.* at 6.

151 CARY FUNK & MEG HEFFERON, PUBLIC VIEWS OF GENE EDITING FOR BABIES DEPEND ON HOW IT WOULD BE USED 3 (2018), https://www.pewresearch.org/science/2018/07/26/public-views-of-gene-editing-for-babies-depend-on-how-it-would-be-used/.

152 *Id.*

were faced with a dissociation of agency over our lives that was truly unparalleled: not being allowed to travel, mandatory masking, shutdowns of businesses for months on end, and a return to work and school being conditioned on three vaccines in a matter of months, with public shaming for noncompliance.

The COVID era also brought a reduction in privacy associated with personal medical decision-making. Vaccine cards and digital vaccine passports were public disclosures of medical records that HIPAA clarified did not fall within its Privacy Rule in many instances.[153] The HIPAA Privacy Rule, which safeguards against unauthorized disclosure of personal medical records, clarified that it does not prohibit any person or entity (outside of covered entities, such as insurance plans or health care providers) from asking about an individual's vaccination status.[154] Anyone from an employer to a host at a restaurant could require you to disclose your vaccination status. What resulted was both mass submission to CDC vaccination recommendations and widespread fraud.[155] Online forums taught those that wanted to avoid state public health and safety regulations how to produce counterfeit vaccination records,[156] resulting in states like New York adopting statutes that criminalized the production of falsified vaccine records.[157] In places where Americans felt that they were not given an option to choose whether or not to take a preventative vaccine, many resorted to extreme measures, such as fraud and forgery, as a means to not feel ostracized in society.[158] Could genomic composition cards be next?

Notwithstanding the elements of illness and losing loved ones for so many Americans, those months inside showed how quickly humanity can adapt and change. If something were to become mandatory, such as genetic intervention, how many voices would withstand being against conformity? A large portion of society was willing to sacrifice a measure of liberty for the public good during the pandemic. Editing the human genome to remove aspects of gene sequencing that contribute to suffering and reduced life expectancy could certainly be sold as a public good. In fact, it could be seen as a deprivation of liberty to be denied such procedures. While the circumstances of COVID and CRISPR are not perfectly analogous, with one being more transient and the other impacting the future of humanity, it is a modern illustration of how quickly reproductive,

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153 *See HIPAA, COVID-19 Vaccination, and the Workplace*, U.S. DEP'T HEALTH AND HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-covid-19-vaccination-workplace/index.html (Sept. 30, 2021).

154 *Id.*; *See* 45 C.F.R. § 160.103 (2023).

155 *See, e.g.*, Press Release, U.S. Dep't of Justice, Two Defendants Charged in Separate, COVID – 19 Vaccination Card Frauds (Sept. 29, 2021).

156 Jaclyn Diaz, *Fake COVID Vaccine Cards Are Being Sold Online. Using One Is a Crime*, NPR (June 8, 2021, 5:47 AM), https://www.npr.org/2021/06/08/1004264531/fake-covid-vaccine-cards-keep-getting-sold-online-using-one-is-a-crime.

157 S.B. 4516, 2021 Leg., 244th Sess. (N.Y. 2021) (enacted).

158 *See* Diaz, *supra* note 157.

parental, and privacy rights can be supplanted on the grounds of human preservation and societal amelioration.

C. No Parent Consent and Artificial Wombs

Where informed consent on behalf of a child is concerned, taking parents out of the equation quickly solves the problem of potential reservations and questions.[159] There may arise a future dystopian reality where women are no longer necessary for human gestation, and actions taken on behalf of artificial embryos are at the full discretion of private organizations.

In 2017, it was reported that American researchers developed a "Biobag," which allowed an extracorporeal pregnancy; a lamb fetus was able to reach full-term in an artificial womb environment.[160] Researchers chose a lamb as their experimental subject for obstetric research because sheep have long gestational periods in comparison to other livestock (on average about five months) and a lamb is approximately the same size as a newborn at birth.[161] While the goal of this study was to develop an artificial gestational environment for premature neonates, other researchers have taken it a step further.[162] Israeli stem cell researchers created synthetic mouse embryos *without* parent gametes, assembled from embryonic stem cells, and then grew the embryos in an artificial womb.[163] In eight days of mouse gestation (about one third of a full-term mouse pregnancy), the embryo grew a beating heart and a rudimentary brain and gastrointestinal tube.[164]

If human embryos, requiring fertilization through human gametes, have the ethical and legal barriers (and potentially constitutional ramifications) barring experimental trials of heritable genomic modification, ex-vivo synthetic

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159 *See, e.g.*, cases cited *supra* note 61 (Where constitutional fundamental rights are found, such as the right to parent, and there is a challenge to government action, the government must demonstrate that their interference is 'necessary' to accomplish some 'compelling government interest'—the highest form of judicial scrutiny. Implied in this constitutional guarantee is that where there are no legal parents, there are no constitutional challenges that the state or federal government must overcome. This gives way for the government to have an uncircumscribed ability to take more extreme action, in an otherwise limited space).

160 Jenny Kleeman, *'Parents Can Look at Their Foetus in Real Time': Are Artificial Wombs the Future?*, THE GUARDIAN (June 27, 2020, 6:00 AM), https://www.theguardian.com/lifeandstyle/2020/jun/27/parents-can-look-foetus-real-time-artificial-wombs-future.

161 *Id.*

162 *See id.*

163 Carolyn Y. Johnson, *Scientists Create Synthetic Mouse Embryos, A Potential Key to Healing Humans*, WASH. POST (Aug. 1, 2022, 5:10 PM), https://www.washingtonpost.com/science/2022/08/01/synthetic-mouse-embryo/.

164 *Id.*

embryos may be key to evading federal regulatory bars. Recall that the FDA is banned from "considering any clinical trial application 'in which a human embryo is intentionally created or modified to include a heritable genetic modification'" in the Congressional Consolidated Appropriations Act of 2016.[165] The definition of "human embryo" is defined in the Dickey-Wicker Amendment as an organism (outside of the human subject parameters of 45 C.F.R. § 46) that results from "fertilization, parthenogenesis, cloning or any other means from one or more gametes or human diploid cells."[166] It appears that embryoids, derived from embryonic stem cells, do not clearly fit within the federal definition of a human embryo. Without the hurdle of being defined as an embryo in the federal regulatory landscape, this opens the door for eventual functional artificial human embryo research and application.

Not only do artificial womb and synthetic embryo births negate the volition of parental discretion and the role of women in human reproduction, they also siphon human essence and experience. This reality diminishes humankind to nothing more than a manufactured commodity, including a capricious commoditization of established foundational human rights.

CONCLUSION

"Then God said, 'Let Us make man in Our image, after Our likeness' . . . So, God created man in His own image; in the image of God He created him."[167] Whether as a society or personally we hold this to be true, the sentiment conveys great meaning. Humanity was created perfectly imperfect, evolving over time with each individuals' traits, character, and values shaping the period they were born into, for better and worse, and forming the spectrum of human diversity.

Man-made technology can change that. Each generation would get "better" according to the social climate of that time and according to legislators that may amend policy on a whim. At the close of each historical event or era we are left with an imprint, encapsulating all of the lessons, mistakes, and triumphs unique to that time period. This imprint can be carefully studied for its strengths and weaknesses, or outright ignored. The definition of human "superiority" historically is troublesome. We must consider the past, the complexities of the present, and a realistic future for a just, circumscribed implementation of CRISPR, both in the United States and abroad. This is particularly true when

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165 Jocelyn Kaiser, *Update: House Spending Panel Restores U.S. Ban on Gene-Edited Babies*, SCIENCE (June 4, 2019), https://www.science.org/content/article/update-house-spending-panel-restores-us-ban-gene-edited-babies.

166 Megan Kearl, *Dickey-Wicker Amendment, 1996*, THE EMBRYO PROJECT ENCYCLOPEDIA (Aug. 27, 2010), https://embryo.asu.edu/pages/dickey-wicker-amendment-1996.

167 *Genesis* 1:26–27.

considering maternal and fetal agency and the future of reproductive rights in America, where the role of the state, the federal government, and individual liberty are in wavering conflict.

The lack of uniformity across the United States with abortion legislation has directly contributed to the shift in classification of an embryo from property to person in many states. When embryos are classified as property, research, authorized clinical trials, and the eventual rollout of germline gene intervention techniques are streamlined. With this metamorphosis in the emerging re-categorization of an embryo, personhood implicates constitutional rights. Where constitutional rights are acknowledged, individual liberty, integrity, and dignity must be respected. Embryos forcibly "corrected" due to a positive test result for a genetic abnormality discriminates against the individual and strips their autonomy. Consistent with the nature of germline gene editing, this not only deprives a person of individual freedoms, but limits the self determination of generations to come—liberties that a living Constitution intends to protect. The human race finds unity in how our biological structure is connate and uniform, from blastula to birth. If there is codification of a right to life in American legislation, there is undoubtedly a right to life with bodily integrity applicable to human embryos that will be implanted.

For these reasons, drafting and codifying regulations requires great scientific debate, opportunities for public comment, and transparent federal regulatory oversight. There are avenues that can be taken to provide national uniformity, which requires both congressional and administrative agency action. Embryonic personhood (in the absence of "Life at Conception" and similar acts to pass through both chambers of Congress) arises from state legislatures and a lack of federal preemption in this area. The Dickey-Wicker Amendment may also need to be re-evaluated; federal funding through the NIH provides standardized research and ethical guidelines across federally funded research projects. Guidelines, such as 45 C.F.R. Part 46, *Protection of Human Subjects*, may need to be amended to include rigid, narrow research standards involving human embryonic germlines. Research and medical practices that engage in genomic therapy have the potential to be regulated by Congress, as affecting interstate commerce, limiting the vast discretion left to individual states, research institutions and private corporations.

In regard to the FDA, as previously stated, Congress prevents this administrative agency from using its annually appropriated funds to consider applications of CRISPR in the human germline. In the relatively near future, the FDA will likely issue a Cellular and Gene Therapy Guidance document that will guide applicants in Investigational New Drug Applications. From that formal statement, applications of gene therapy to genetic enhancement and outlier

treatments could be strictly prohibited, while permitting usage solely in the prevention of serious diseases and congenital conditions. This results in only implementation to well-studied single gene disorders and certain polygenic conditions existing naturally in the human genome, along with individuated mutational variations known to be tied to the expression of severe, debilitating genetic diseases.

This leaves the consideration of parents' rights, which permits two potential courses of action. The first allows a parent to decide what is in the best interest of their child, if it is medically determined that the embryo has mutations known to cause disorders falling within the FDA's allowances. A parent's consent could result in preventing the passage of genetic mutations, or the lack of such consent could remove the option. The second places the discretion to intervene with the medical provider or the state, as a public health measure. There are numerous moving parts to this issue, but where fundamental rights are observed or contemplated, strong legal safeguards are imperative to mitigate against a pullulation of potential issues.

On the precipice of trimming "undesirable" genetic sequencing in the human genome, will a lack of foresight foster selfishness, radical configurations of the "human ideal," and ostracization of those not in conformity with that ill-construed standard? Or will legislators and scientists proactively consider these evils and regulate CRISPR-Cas9 for the better, allowing for the advancement of medicine within reasonable boundaries?

With all the possibilities that may result from unlocking this pithos, may we not be so drowned in roseate reverie that we are unable to see the potential for transcendent curses, or so concentrated on corruption that we lose sight of hope.